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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/621,435 | 07/17/2003 | Janet Codd | DOVP-1-0901 | 1728 |

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| EXAMINER | |
|---|---|
| ROGERS, JAMES WILLIAM | |
| **ART UNIT** | **PAPER NUMBER** |
| 1618 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 02/01/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/621,435 | CODD ET AL. | |
| | Examiner | Art Unit | |
| | James W. Rogers, Ph.D. | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *10-13,16-18,26-36 and 45-49* is/are pending in the application.

4a) Of the above claim(s) *2-4,6-8,15,19-25 and 37-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13,16-18,26-36 and 45-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/15/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election of Group II with traverse in the reply filed on 12/18/2006is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The examiner acknowledges applicants election of the range set forth in claim 33 for the dissolution profile. Besides the claims withdrawn by applicants the examiner has withdrawn claims 37-44 as pertaining to non-elected material. Currently claims 10-13,16-18,26-36 and 45-49 are pending.

### *Claim Objections*

Claim 17 is objected to because of the following informalities: the recitation of "pharmaceutically carrier composition" is not in proper grammatical form and is probably a typo, the examiner suggests amending the claim to "pharmaceutical carrier composition", to render this objection moot. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26,29-33,35-36,45,47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Dietrich et al. (US 2004/0058896 A1).

Dietrich teaches a pharmaceutical preparation comprising an active (including bicifadine hydrochloride) and 1-25% of a polymer including HPMC. See [0002],[0010],[0030],[0407]-[0408] and [0411]. Regarding claims 30,33,37,41,45 and 49 the limitations on the rate of release, dissolution profile and Cmax are all limitations of an intended use, the claims recite a composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Thus since Dietrich discloses the same active and the same polymer it meets the limitations on the rate of release, dissolution profile and Cmax. Besides the argument above it is inherent that as claimed any composition comprising the same active (bicifadine) and the same slow release polymer (HPMC) as applicants claimed invention will meet any claimed limitation in regards to its measured dissolution profile, rate of release and Cmax after it is ingested within the body.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-13,16-18,26-36,45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fanshawe et al. (US 4,231,935, disclosed by applicants) in view of Dietrich et al. (US 2004/0058896 A1).

Fanshawe discloses substituted 3-azabicyclohexanes including bicifadine, the azabicyclohexanes could be formulated into oral dosage forms such as tablets containing between 10 to 400 mg of the active and binders such as dicalcium phosphate (a calcium phosphate). See col 20 lin 42-col 21 lin 16 and example 36. Regarding claim 17 Fanshawe discloses that the active can comprise anywhere between about 5% to 75% or more of the weight of the dosage form, it is therefore obvious that the rest of the dosage form would comprise the other excipients including the binder, therefore the skilled artisan could through routine experimentation form the disclosed percentages come up with the same amount of carrier as applicants currently claimed invention. Besides the above argument generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the

prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Fanshawe while disclosing several excipients does not disclose the use of HPMC in the oral dosage form.

Dietrich is disclosed above. Dietrich is used to primarily show that oral dosage forms containing analgesics such as bicifadine hydrochloride and HPMC was already well known in the art at the time of the invention. The advantages of the preparations disclosed within Diethrich were a controlled release rate, high stability, good compressibility and a uniform delivery of the active ingredient.

It would have been prime facie obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Fanshawe discloses all of applicants claimed invention except for the use of HPMC while Dietrich showed that it was already well known at the time of the invention that oral dosage forms contained bicifadine and HPMC. The motivation to combine the above documents would be to prepare a bicifadine controlled release oral dosage form. The advantage of such a dosage form would be delivery to a patient in

need the analgesic agent bicifadine with the benefit of a controlled release and uniform delivery. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

**Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER